

## **REMARKS**

### **I. Status of the Application**

This is a response to the Office Action mailed on October 20, 2008. By way of this response, Claims 60-70 are now pending. Claims 18 and 19 were previously withdrawn and Claims 1-17 and 20-59 are cancelled herein. Claim 60 has been amended to add the limitations of cancelled Claim 1 and Claim 70 has been added. Support for the amendments can be found throughout the specification and claims as originally filed. No new matter is presented by way of the amendments.

### **II. Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 1-17, 20-33 and 52-69 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly “containing subject matter which was not described in the Specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention.” Specifically, the Examiner argued that the “Specification does not reasonably provide enablement for the methods of prevention within the full scope of the claimed compounds.”

Without conceding to the appropriateness of this rejection and solely to expedite prosecution of this application, Applicants have amended the claims to exclude the “prevention” of GERD. Applicants assert that these amendments render this rejection moot. Therefore, withdrawal of this rejection is respectfully requested.

### **III. Rejections Under 35 U.S.C. § 103(a)**

The outstanding Office Action states that claims 1-17, 20-33, and 52-59 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,489,346 (“the ‘346 patent”) in view of Hatlebakk et al. Claims 1-17, 20-33, and 52-59 are also rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 2003/0191159 A1, in view of Hatlebakk et al. However, on April 1, 2009 the Examiner notified the undersigned that all of the pending claims should have been rejected under 35 U.S.C. § 103(a) based on these references.

In the Office Action, the Examiner states that “Phillips does not disclose *per se* the

administration of the proton pump inhibitor compositions within about 60 minutes prior to a meal, as required by the instant claims.” Office Action at p. 9. Instead, the Examiner relies on Hatlebakk et al. for this limitation in the pending claims. In this regard, the Examiner states that “Hatlebakk et al. teach the administration of the proton pump inhibitors, omeprazole and lansoprazole, 15 minutes prior to a meal, to provide better acid suppression.” *Id.* Applicants respectfully assert that the Examiner incorrectly arrives at the conclusion that it would have been obvious to one of ordinary skill in the art to combine these two references.

The enteric coated omeprazole in the 20 mg capsule from Astra-Zeneca and the enteric coated lansoprazole in the 30 mg capsule from TAP Pharmaceuticals used in Hatlebakk are significantly different than compositions comprising “non-enteric coated” proton pump inhibitors as presently claimed and disclosed in Phillips. The Examiner has provided no evidence that one of skill in the art would have been motivated to combine references describing these significantly different compositions together. Nor has the Examiner shown that one of skill in the art would have expected the very different compositions described in the two references cited to have the same benefit if dosed before a meal. Applicants assert that one of skill in the art would not have expected the compositions described in Phillips and Hatlebakk to behave the same way. This is in part because the absorption of an enteric coated proton pump inhibitor occurs substantially later than a non-enteric coated proton pump inhibitor. In light of this, Applicants assert that one of skill in the art would not have been motivated to combine the references relied on by the Examiner and respectfully request withdrawal of this rejection.

#### **IV. Obviousness-Type Double Patenting**

Claims 1-17, 20-33 and 52-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 13-39, 41, 44, 45 and 47-63 of copending Application No. 10/938,766; claims 44-85 of copending Application No. 10/893,092; claims 1-35 of copending Application No. 11/107,349; claims 1-15, 17, 18, 20-25, 54, 56-86 of copending Application No. 10/893,203; claims 48-58 of copending Application No. 11/138,763; and claims 1-55 of copending application No. 10/982,369.

Applicants respectfully assert that the amendments made herein render this rejection moot. Nevertheless, without conceding to the appropriateness of this rejection, Applicants will

consider submitting a terminal disclaimer once allowable subject matter is indicated if necessary at that time.

**CONCLUSION**

For at least the foregoing reasons, Applicants submit that the presently pending claims are in condition for allowance and request early and favorable consideration. Further, none of Applicants' amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned attorney at (858) 350-2319 with any questions or to otherwise expedite prosecution.

Respectfully submitted,

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